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Proposed Maximum Residue Limit PMRL2016-05

Clothianidin

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing to establish maximum residue limits (MRLs) for clothianidin on tuberous and corm vegetables (CSG 1C), leafy vegetables (except *Brassica* vegetables) (CG 4), *Brassica* (cole) leafy vegetables (CG 5), pomegranates, figs, rice and tea (dried leaves) to permit the import and sale of foods containing such residues.

Clothianidin is an insecticide currently registered in Canada for use on various commodities.

The PMRA must determine the quantity of residues that are likely to remain in or on the imported food commodities when clothianidin is used according to label directions in the exporting country, and that such residues will not be a concern to human health. This quantity is then legally established as an MRL on the corresponding imported commodity. An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for clothianidin is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by Canada's Notification Authority and Enquiry Point.

The proposed MRLs, to replace or be added to the MRLs already established for clothianidin, are as follows.

Table 1 Proposed Maximum Residue Limits for Clothianidin

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Clothianidin	[C(*E*)]-*N*-[(2-chloro-5-thiazolyl)methyl]-*N'*-methyl-*N"*-nitroguanidine	70	Tea (dried leaves)
		3[2]	Leafy Vegetables (except *Brassica* Vegetables) (Crop Group 4)
		1.9	*Brassica* (cole) leafy vegetables (Crop Group 5)
		0.3[3]	Tuberous and Corm Vegetables (Crop Subgroup 1C)
		0.2	Pomegranates
		0.05	Figs
		0.01	Rice

[1] ppm = parts per million.
[2] The recommended import MRL of 3 ppm for CG 4 will replace the MRLs of 0.2 ppm (head lettuce) and 0.5 ppm (leaf lettuce).
[3] The currently established MRL of 0.3 ppm in/on potatoes and sweet potato roots will be extended to the whole crop subgroup 1C

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

Table 2 compares the MRLs proposed for clothianidin in Canada with corresponding Codex MRLs.[1] The MRLs proposed for clothianidin in Canada are the same as corresponding tolerances in the United States, in accordance with American tolerances listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

Table 2 Comparison of Canadian MRLs and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	Codex MRL (ppm)
Tuberous and Corm Vegetables (CSG 1C)	0.3	0.2 (root & tuber vegetables)
Leafy Vegetables (except *Brassica* Vegetables) (CG 4)	3	2 (leafy vegetables) 0.04 (celery)
Brassica (cole) leafy vegetables (CG 5)	1.9	0.2
Pomegranates	0.2	Not Established
Figs	0.05	Not Established
Rice	0.01	0.5
Tea (dried leaves)	70	0.7

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for clothianidin up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

Residue data for clothianidin in head lettuce, leaf lettuce, spinach, celery, cabbage, cauliflower, mustard greens, pomegranates, figs, rice and tea were submitted to support the maximum residue limits on imported leafy vegetables (except *Brassica* vegetables) (CG 4), *Brassica* (cole) leafy vegetables (CG 5), pomegranates, figs, rice and tea (dried leaves). In addition, processing studies in treated rice grain and fresh tea leaves were reviewed to determine the potential for concentration of residues of clothianidin into processed commodities.

Previously reviewed residue data from field trials conducted in/on potatoes, head lettuce and leaf lettuce were reassessed in the framework of this petition to support the importation from U.S.A. of tuberous and corm vegetables (CSG 1C) and leafy vegetables (except *Brassica* vegetables) (CG 4). In addition, processing studies in treated potatoes were also reassessed to determine the potential for concentration of residues of clothianidin into processed commodities.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for clothianidin was based upon the residues observed in crop commodities treated according to label directions [or to exaggerated rates] in the exporting country, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs for imported tuberous and corm vegetables (CSG 1C), leafy vegetables (except Brassica vegetables) (CG 4), *Brassica* (cole) leafy vegetables (CG 5), pomegranates, figs, rice and tea (dried leaves).

Table A1 Summary of Field Trial and Processing Data Used to Support MRLs

Commodity	Application Method/Total Application Rate (g ai/ha)[1]	Preharvest Interval (days)	Lowest Average Field Trial Residues (ppm)	Highest Average Field Trial Residues (ppm)	Experimental Processing Factor
Potato tubers	Seed-piece treatment; 11.8-12.0 g ai/100 kg seed	90	<0.02	0.23	1.4-fold in wet potato peel; 2.6-fold in potato chips; 6.4-fold in potato granules/flakes
	Seed-piece treatment; 18.75 g ai/100 kg seed	79-143	<0.01	0.086	
Head lettuce	Foliar; 317-326	5-8	<0.02	0.101	None
Leaf lettuce	Foliar; 314-326	7	0.073	0.255	
Head lettuce with wrapper leaves	Foliar; 221-228	7	0.012	0.527	

Commodity	Application Method/Total Application Rate (g ai/ha)[1]	Preharvest Interval (days)	Lowest Average Field Trial Residues (ppm)	Highest Average Field Trial Residues (ppm)	Experimental Processing Factor
Leaf lettuce	Foliar; 222-226	7	0.214	1.10	
Spinach	Foliar; 216-228	6-7	0.080	1.73	
Celery (petioles with leaves)	Foliar; 222-231	7	0.027	0.924	
Cabbage head with wrapper leaves	Foliar; 222-228	6-7	0.013	0.367	None
Cauliflower head and stem	Foliar; 223-228	7	0.014	0.061	
Mustard greens leaves	Foliar; 218-226	7	0.141	1.31	
Pomegranates (fruits)	Foliar; 224	7	0.042	0.075	None
Figs (fruit)	Foliar; 224	7	0.017	0.029	None
Rice (grain)	Seed treatment,[2] 329-348	119-127	<0.01	<0.01	2.8-fold in rice hulls; 0.06-fold in polished rice; 0.19-fold in rice bran
Tea (dried leaves)	Foliar; 320-480	7	2.19	36.1	None

[1] g ai/ha = grams of active ingredient per hectare. [2] The US registered use pattern on rice is a seed treatment.

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of clothianidin. Residues of clothianidin in these imported crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.